From: Barry Cadden
Sent: Wednesday, July 25, 2012 1:50 PM
To: scarter@neccrx.com
Subject:

What your not seeing, is what we are not currently doing , but should be doing.

Example:

Make beta repos(p)= certain lot# (no SKU#..yet)....test s/e/q...then(we test before we fill any vials just in case the lot is "bad"....we would then waste tons of vials!

a) Run lot for 10ml vial fill process= new lot# + specific SKU#.....fill say #1000 x 10ml vials + test again for (S/E) .....we now cover potential problems in fill process, specific tech or Rph....etc.
b) Run lot for 5ml.....etc..i do not see a reason to test quantitative "multiple " times.....do u?

The only difference is now we have quantitative for "stock" lot# and qualitative for specific lot. We are now truly covered = no more large holes in process.
We can't forget that the device, tech, Rph, day of the week.....etc. all comes into play and we are not covering these things all the time in current testing method.